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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/623,801

07/22/2003

Peter Forsell

2333-122

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07/01/2009

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EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

07/01/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/623,801 | Applicant(s) FORSELL, PETER | |
| | Examiner DIANE YABUT | Art Unit 3734 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-56,58-77 and 80-155 is/are pending in the application.
- 4a) Of the above claim(s) 5-16,20-55,61-77 and 80-82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,17-19,56,58-60 and 83-155 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to applicant's amendment received on 04/02/2009.

The examiner acknowledges the amendments made to the claims.

Claims 1, 5-56, 58-77, and 80-155 are pending in this application. Claims 5-16, 20-55, 61-77, and 80-82 are withdrawn from consideration.

Double Patenting

1. Applicant is advised that should claims 99-102 be found allowable, claims 103-106 will be objected to under 37 CFR 1.75 as being substantial duplicates thereof.

When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 17-19, 56, 58-60, and 83-155 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Vincent** (U.S. Pat. No. **5,601,604**) in view of **Furst** (U.S. Pub. No. **20020099438**).

Claims 1, 17-19, 56, 58-60, and 83-155: Vincent discloses the claimed device, an implantable constriction device for forming a restricted stoma opening in the stomach of

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a patient, comprising an elongate composite structure or elongate means adapted to externally constrict the stomach of the patient, wherein said elongate composite structure comprises an elongate member **15**, a base material **16** surrounding the elongate member, the base material making said structure self-supporting, an adjustment means **19** adapted to adjust the elongate member, or to mechanically adjust the non-inflatable composite structure to either enlarge or restrict the stoma opening (Figures 1-2), *except for* the device having property improving means for improving at least one physical property of said composite structure other than self-supporting properties, said property improving means including at least one layer applied on said base material intended to contact the stomach, and improving the anti-friction properties of said constricting means, as well as liquid impermeability, softness, strength, fatigue resistance, aggressive body fluid resistance, anti-friction properties, the layer being selected from a group consisting of a biocompatible metal layer or a viscoelastic material.

Furst teaches property improving means comprising a coating or layer on a base material at least along a side of said elongate composite structure that is capable of contacting the stomach, said coating having better aggressive body fluid resistant properties than said base material, said coating being selected from the group consisting of a TeflonTM (polytetrafluoroethylene), ParyleneTM, and a biocompatible metal coating selected from the group consisting of gold, silver, and titanium, and that biocompatible coatings are used to reduce inflammation, infection, irritation, and/or rejection of the device (page 5, paragraph 17). It would have been obvious to one of

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ordinary skill in the art to provide a coating on the elongate structure, as taught by Furst, to Vincent in order to reduce inflammation, infection, irritation, and/or rejection of the device.

Although Furst does not teach a property improving viscoelastic layer, it would have been obvious to one of ordinary skill in the art to provide a layer surrounding the device of Vincent made of a biocompatible material that reduces the likelihood of injuring or damaging tissue during contact, such as silicone gel, cellulose gel, or collagen gel.

Response to Arguments

3. Applicant's arguments filed 04/02/2009 have been fully considered but they are not persuasive.

4. Applicant generally argues that the references either individual or in combination do not disclose an implantable constriction device that includes an elongate member that is *surrounded* by a base material, but rather a stomach-facing base material surface **15** coextensive with the elongate member surface **16** in Vincent. However, this elongate member **15** may be considered to be surrounded by or encircled by the base material **16**, and not necessarily encapsulated by or enclosed by the base material, and therefore reads on this limitation.

5. Applicant also argues that the combination of Vincent with Furst would not have occurred to one of ordinary skill in the art since Furst involves a stent with coatings that overcomes biological problems during implantation of the stent rather than improving

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physical properties of the stent, and is not used in the stomach. However, it was well known in the art to provide beneficial coatings on implants, including gastric bands or stents, and one of ordinary skill in the art would have considered the teaching of Furst directed at using biocompatible materials to reduce inflammation, infection, irritation, and/or rejection of the implant (page 5, paragraph 17), one of the materials including Teflon (polytetrafluoroethylene) which is known for its physical property of flexibility. Therefore, given the advantageous aspects of using these coatings in Furst, one of ordinary skill in the art would have modified the elongate band of Vincent with physical property improving means of Furst.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734